K080162

APR 22 2008

MIS

510(k) Summary:

Uno - One Piece Screw-Type Dental Implant

Company Name -
MIS - Implants Technologies Ltd.
POB 110 Shlomi Industrial Zone
Shlomi 22832
ISRAEL
Telephone: +972-4-980-9966
Fax: +972-4-980-9944

Establishment Registration Number: 3004203816

Contact Name: Iman Khorshid
Quality Manager
Telephone: +972-4-980-9966
Fax: +972-4-980-9944
E-mail: iman@mis-implants.com

US Agent: Motti Weisman - VP Marketing
MIS Implants Technologies Inc.
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Elmwood Park, NJ 07407
Phone: (201) 797-9144
Fax: (201) 797-9145
E-mail: mis.service@verizon.net

Date prepared: January 17, 2008

Trade Name: Uno - One Piece Screw-Type Dental Implant

Classification name: Implants, Endosseous, Root Form

Common/usual name: Uno - One Piece Screw-Type Dental Implant

Product Code: DZE

Regulation No.: 872.3640

Class: II

Panel identification: Dental Devices Panel

Predicate Device:
ZIMMER DENTAL ONE-PIECE IMPLANT **from ZIMMER DENTAL INC. , 1900 Aston ave. Carlsbad, CA 92008, cleared under 510(k) no. K052997.**

Description of the device:

The Uno - One Piece Screw-Type Dental Implant is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices such as artificial teeth, in order to restore the patient chewing function. The Uno - One Piece Screw-Type Dental Implant is made of one piece solid material comprised of the implant and abutment combination.

The Uno implants are provided in two diameters. The Uno 3.0 mm dental implant is indicated for placement in the mandibular central, lateral incisor and maxillary lateral incisor regions. The Uno 3.5 mm dental implant is indicated for placement in the premolar, cuspid and incisor regions.

The Uno implants are manufactured of Titanium alloy Gr. 5 complying with standard ASTM F136-02. The Implants are provided in several lengths of 10mm, 13mm and 16mm with diameters of 3.0mm, 3.5mm. The implants surface is sand blasted and acid etched to improve the osseointegration. The implants are tapered with double thread (2mm pitch) for fast insertion.
The Uno implants are supplied sterile and are intended for single use only.

Indications for Use:
The Uno - One Piece Screw-Type 3.0 mm Dental Implant is indicated for use in surgical and restorative applications for placement in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws, to provide support for prosthetic devices such as artificial teeth, in order to restore the patient chewing function. The Uno - One Piece Screw-Type 3.0 mm Dental Implant is made of one piece solid material comprised of the implant and abutment combination.

The Uno - One Piece Screw-Type 3.5 mm Dental Implants are indicated for use in surgical and restorative applications for placement in the premolar, cuspid and incisor regions of partially edentulous jaws, to provide support for prosthetic devices such as artificial teeth, in order to restore the patient chewing function.
The Uno - One Piece Screw-Type 3.5 mm Dental Implants are made of one piece solid material comprised of the implant and abutment combination.
The Uno implants are manufactured of Titanium alloy Gr. 5 complying with standard ASTM F136-02.

Substantial Equivalence:
The Uno - One Piece Screw-Type Dental Implants have the same intended use as the ZIMMER DENTAL ONE-PIECE IMPLANT **from ZIMMER DENTAL INC., 1900 Aston ave. Carlsbad, CA 92008, cleared under 510(k) no. K052997**, and have equivalent performance characteristics. Both products are manufactured from the same Titanium alloy. All other technological characteristics are similar and show equivalent performance capabilities. The Uno - One Piece Screw-Type Dental Implants are therefore substantially equivalent to the predicate device.

Conclusion -
The evaluation of the Uno - One Piece Screw-Type Dental Implants does not raise any additional concerns regarding safety and effectiveness and may therefore be considered substantially equivalent to its predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 22 2008

Ms. Iman Khorshid
Quality Manager
M.I.S. Implants Technologies Limited
P.O.BOX 110
Shlomi Industrial Zone
Shlomi 22832
ISRAEL

Re: K080162
Trade/Device Name: Uno – One Piece Screw-Type Dental Implant
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Codes: DZE
Dated: March 20, 2008
Received: March 31, 2008

Dear Ms. Khorshid:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

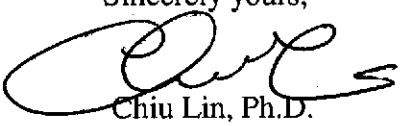
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K080162

INDICATIONS FOR USE

510(k) Number (if known): K080162

Device Name: Uno - One Piece Screw-Type Dental Implant

Indications for Use: The Uno - One Piece Screw-Type 3.0 mm Dental Implant is indicated for use in surgical and restorative applications for placement in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws, to provide support for prosthetic devices such as artificial teeth, in order to restore the patient chewing function. The Uno - One Piece Screw-Type 3.0 mm Dental Implant is made of one piece solid material comprised of the implant and abutment combination. Mandibular central and lateral incisors must be splinted if using two or more 3.0 mm implants adjacent to one another. The Uno implants are manufactured of Titanium alloy Gr. 5 complying with standard ASTM F136-02.

The Uno - One Piece Screw-Type 3.5 mm Dental Implants are indicated for use in surgical and restorative applications for placement in the premolar, cuspid and incisor regions of partially edentulous jaws, to provide support for prosthetic devices such as artificial teeth, in order to restore the patient chewing function. The Uno - One Piece Screw-Type 3.5 mm Dental Implants are made of one piece solid material comprised of the implant and abutment combination. The Uno implants are manufactured of Titanium alloy Gr. 5 complying with standard ASTM F136-02.

Prescription Use ___X___ OR Over the Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sharon Ruop

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K080162